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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,713	11/27/2000	Dale B. Schenk	15270J-004741US	9870

20350 7590 03/26/2002

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EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/723,713	Schenk et al
Examiner	**Art Unit**
Sharon L. Turner, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 10-12-01

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 33 and 34 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 33 and 34 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Priority

1. Applicant's claims for domestic priority under 35 U.S.C. 119(e) are acknowledged. However, the provisional applications (60/067,740 filed 12-2-1997 and 60/080,970 filed 4-7, 1998) upon which priority is claimed were filed more than 12 months prior to the filing date of the parent application (09/322,289 filed 5-28-1999) and thus fail to comply with the requirements for priority under 35 U.S.C. 119(e). Thus, the effective filing date is that of 09/322,289, filed 5-28-1999. If there is an intervening priority application to which applicant's are entitled benefit, it should be claimed in order to provide continuity with the provisionals.

Information Disclosure Statement

2. It is noted that Applicant's have relied on the ability of the Examiner to obtain copies of the IDS references as filed in parent application 09/322,289. However it is noted that the IDS filed 10-9-01 is more extensive than in the '289 application, (it contains references which are not cited on a relevant PTO-1449 in the parent). It is also noted that in the parent application it was indicated that, "The IDS submissions have been considered to the extent as indicated on the attached 1449s. The examiner notes that some of the references are in improper format or have been separated from the file. Applicants are requested to supply the absent information and references or to present the post-card receipt for such filing in the next communication." Thus it has been determined that a substantial portion of the references now cited, do not comply 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that

portion which caused it to be listed; and all other information or that portion which caused it to be listed. The PTO 1449 has been placed in the application file, but the information referred to therein has only been considered to the extent as indicated on the PTO-1449 (as supported by the parent). Applicants should submit copies for those references not submitted in either instant application or in the parent, and should rectify the outstanding issues concerning the IDS in instant and/or the parent application by either filing copies of the omitted references or submitting a post-card receipt for the submission.

Claim Objections

3. Claims 33-34 are objected to under 37 CFR 1.75(c), as depending from a canceled base claim.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

The specification fails to disclose any nucleic or amino acid sequences. In particular, no sequences which specifically encode either the heavy or light chains of an antibody which would specifically bind to an amyloid deposit.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

Thus, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic and amino acid sequences and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific nucleic and amino acids are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

6. Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears (as drawnt to canceled claim 1) to be drawn to a method of preventing or treating disease via in vivo nucleic acid expression of recombinant antibody molecules. However, as noted by Peterson et al., 1996 Feb., Lab. Animal Sci., 46(1):8-14, p. 9, column 1, last paragraph, lines 4-6, "because of their (antibodies) large size and difficulty in proper protein folding, functional complete immunoglobulin molecules could not be produced in bacteria." The specification fails to exemplify the particular nucleic acids essential to encode the relevant antibody molecule and fails to teach the essential methods of expression in a host cell, particularly in a patient as the claim is drawn. Further, the claim encompasses the prevention or treatment of any disease associated with amyloid deposition. However, the specification only discloses antibody capable of binding beta-amyloid and which may be useful in decreasing amyloid burden in brain. Yet the output measurement fails to correspond to the activities noted in the claim 1, i.e., an antibody capable of preventing or treating a disease characterized by

amyloid deposit in a patient. The clinical and neuropsychological manifestations of Alzheimer's are reflected in Morris et al., Neurology, September 1989, 39:1159-65. Yet the specification fails to show the amelioration, treatment or prevention of any clinically symptomatic measurement of Alzheimer's as disclosed. Thus, the skilled artisan would be forced into further undue experimentation not only to determine a method of antibody delivery via nucleic acid but to verify and determine the relevant antibodies and any clinically relevant effects which are either treated or prevented via such treatment for any particular amyloid deposition disease, inclusive not only of beta-amyloid deposition in Alzheimers, but of amyloid deposition for example in amyloid angiopathy of the vascular or immune systems.

Thus, in view of the lack of guidance in the prior art, lack of examples, and lack of predictability in treatment of diseases, one skilled in the art would be forced into further undue experimentation to determine those antibodies relevant to the particular method, i.e., which are capable of preventing or treating a disease characterized by an amyloid deposit in a patient, to determine the relevant antibodies' amino and nucleic acid sequences, and further determine a means of expression in a patient such that the nucleic acid administered to the patient actually produces and "administers" the antibody as claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-34 recites the limitations "the antibody" and "the patient" in reference to claim 1. However, there is no claim 1 and therefore there is insufficient antecedent basis for these limitations in the claim.

9. Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the particular nucleic acid and the means of expression.

Status of Claims

10. No claims are allowed.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The

examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Sharon L. Turner, Ph.D.

March 25, 2002